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PACLITAXEL ELUTING BALLOON AFTER BARE METAL STENT IN ST ELEVATION MYOCARDIAL INFARCTION (THE PEBSI STUDY)

Oral Contributions
Room 8
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Background: Drug eluting stents decrease the rate of restenosis, however, concerns still remains about their safety, especially in ST-segment elevation myocardial infarction (STEMI). The quest for new devices and procedures, aiming for an improved safety/efficacy balance, in STEMI is still warranted. The aim of this study was to evaluate the safety and efficacy of a paclitaxel eluting balloon (PTX-B) treatment after bare metal stent (BMS) implantation (PTX group) as compared to BMS only implantation (BMS group) in patients undergoing primary angioplasty for STEMI within 12 hours of onset of symptoms.

Methods: The PEBSI study was a randomized, multicenter, prospective, single blind, open study. After artery re-permeabilization and successful BMS implantation, patients were randomized in a 1:1 ratio to one of the following groups: PTX group: post-dilatation with a PTX-B (Pantera Lux ®) for 45 seconds. BMS group: no post-dilatation. Late Luminal Loss (LLL) at 9 months was the primary endpoint.

Results: 223 patients were aleatorized (BMS group:112, PTX group:111). The primary endpoint, in-stent late-luminal loss at 9 months follow up angiography, was met: 0.85+0.67 mm in the BMS group vs. 0.32+0.49 mm in PTX group, p<0.0001. Binary restenosis was also significantly lower in the PTX group (29.8% vs 2.2%, p<0.0001). Clinical 12 months follow up was complete in 212 patients: BMS group: 105(95,5%), PTX group:105(95,4%). MACE and isquemia driven TVF and TVR were significantly lower in the PTX-B group (12.5% vs 3.6%, p:0.0156, 11.6% vs 3.6%, p: 0.0256 and 8.9% vs 1.8%, p: 0.0192, respectively). There was a tendency to a lower TLR in the PTX group: 7.1% vs 1.8%, p: 0.05. There was only one late stent thrombosis in the PTX group in a patient who stopped taking all medications.

Conclusion: PTX lesion impregnation, released from a balloon after implantation of a BMS shows angiographic superiority compared with BMS only strategy. Differences in favor the PTX-B over BMS in this study were not limited to angiographic efficacy but also driven by a reduction in clinical ischemic endpoints with very low rates of adverse safety outcomes. PEBSI trial (NCT01839890)